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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/526,417      | 05/13/2005  | Laurent Sandrin      | BDM-05-1038         | 3075             |

35811 7590 03/02/2007  
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| EXAMINER |
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BROWN, HELENE C

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3768

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 03/02/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

EP

|                              |                 |                |  |
|------------------------------|-----------------|----------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s)   |  |
|                              | 10/526,417      | SANDRIN ET AL. |  |
|                              | Examiner        | Art Unit       |  |
|                              | Helene Brown    | 3768           |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/02/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 10/526417, filed on 5/13/2005.

### ***Acknowledgement of Preliminary Amendments***

2. For the record, acknowledgement is made of the applicant's preliminary amendments to the specification and the claims under 37 CFR 1.115. The amendments to the specifications are also acknowledged. In addition, it is acknowledged that applicant cancelled claims, 1-26. Under examination are the newly amended claims, 27-53.

### ***Information Disclosure Statement***

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Drawings***

4. The drawings were received on 04/04/2005. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following

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reference sign(s) mentioned in the description: Element 15 not located in the drawings.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "D" has been used to designate both 1.5 bar and 1.75 bar. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "14" has been used to designate both the x-axis and the y-axis. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

1. The disclosure is objected to because of the following informalities:
  - a. Paragraph [0060] – wrong symbol used in equation "8"; --i--
  - b. Paragraph [0061] – "consequence" misspelled; --consequence—
  - c. Paragraph [0071] – wrong symbol used in equation " $x_2=7$ ", --y--

Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 27-30, 33, & 39 are rejected under 35 U.S.C. 103(a) as being anticipated by Ophir'070 (US Patent No. 5,474,070).

**Claim 27:** Ophir'070 teaches a device for measuring elasticity of a human or animal organ, or viscoelastic environments (Col. 4, Line 22-33) presenting an ultrasonic signal after ultrasonic illumination and consecutively establishing a representation in two or three dimensions of the elasticity (Col. 7, Line 2-14). Ophir'070 teaches at least one

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ultrasonic bar comprising a plurality of transducers (Col. 23, Line 38-39). Ophir'070 teaches an excitor that has a user adjustable speed and frequency (Col. 9, Line 6-10). Therefore, the device taught by Ophir'070 is the functionally equivalent to the invention and is capable of generating and delivering a low-frequency, direct or indirect applied force (Col. 8, Line 65-67). Ophir'070 teaches a receiver that acquires ultrasonic signals (Col. 29, Line 22-24). Ophir'070 teaches a controller that commands and processes data (Col. 23, Line 59 – Col. 24, Line 6). Ophir'070 teaches a scanner that carries out scanning with the bar in one dimension (1D) or in two dimensions (2D) in two perpendicular directions respectively to obtain a representation of the measure of the elasticity in two (2D) or three dimensions (3D) (Col. 7, Line 2-14, Col. 12, Line 35-47 & Col. 18, Line 63-67).

**Claim 28/27:** Ophir'070 teaches an excitor generates a mechanical vibration that can be transversal, longitudinal or a mixture of both (Abstract, Col. 8, Line 37-45, Col. 8, Line 63-67 & Col. 17, Line 50-56 & Line 63-65).

**Claim 29/27:** Ophir'070 teaches an excitor generates a remote palpation using pressure of radiation either with the transducer(s) used for acquiring ultrasonic signals or several transducers arranged around the viscoelastic environment (Col. 11, Line 8-10).

**Claim 30/27:** Ophir'070 teaches an excitor generates internal movements of the human or animal body (Col. 8, Line 39-45).

**Claim 33/27:** Ophir'070 teaches a space between the ultrasonic bar and the viscoelastic environment is constituted at least in part of water or any other element

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capable of assuring free passage of ultrasonic waves (Col. 10, Line 10-11 & 55-58 & Figure 6, Element 203).

**Claim 34/28/27:** Ophir'070 teaches a mechanical vibration is obtained by one or several vibrating plates, piston(s) and/or bar(s) (Figure 8, Element 256).

**Claim 39/27:** Ophir'070 teaches the device comprising two ultrasonic bars (Col. 23, Line 38-39).

5. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ophir'070 and further in view of Sarvazyan'731 (US Patent No. 5,810,731).

**Claim 31/27:** Ophir'070 teaches the excitor comprising one or several transducers, with the transducer(s) used for acquiring ultrasonic signals (Col. 11, Line 8-10). Ophir'070 fails to teach the transducers being hyperthermal. However, hyperthermal is in reference to an elevation in temperature as explain by the applicant in Page 6 Paragraph [0014]. According to Steven L Jacques of the Oregon Graduate Institute of Science and Technology, he defines optoacoustic imaging as characterized by "a temperature rise" (Jacques, Steven L. and Guenther Paltauf. "Optoacoustic imaging: What is optoacoustic imaging?" Oct 2000. Oregon Medical Laser Center. 8 Feb. 2007 <<http://omlc.ogi.edu/news/oct00/saratov2000/intro.html>>.) Sarvazyan'731 teaches the use of optoacoustic pulses in use for elasticity imaging (Col. 5, Line 43-47) for the generation of focused monopolar acoustic pulses (Col. 6, Line 24-27). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teaching of Ophir'070 and Sarvazyan'731 in order to provide an increase in

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radiation force as compared with an ultrasonic pulse of the same energy (Col. 5, Line 54-57).

6. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ophir'070 and further in view of Varghese'075 (US Patent No. 7,166,075).

**Claim 32/27:** Ophir'070 teaches transducer that focuses at a plurality of different points of elevation and scanning is achieved by ultrasonic focalization (Col. 7, Line 15-24, Col. 19, Line 59-67 & Col. 26, Line 3-5). Ophir'070 fails to teach the ultrasonic bar is a 1.5 D bar. However, Verghese'075 teaches the 1.5 D transducers. It would have been obvious to one of ordinary skill in the art to combine the teachings of Ophir'070 and Varghese'075 in order to have a transducer suitable for the image generating process (Col. 4, Line 38-39).

7. Claim 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ophir'070 and further in view of Sandrin'417 (US Patent Application No. 10/526417).

**Claim 35/27:** Ophir'070 teaches a receiver comprises ultrasonic transmitters and receivers, digital-to-analog (CNA) (Figure 6, Element 209 & Col. 23, Line 55-56). Ophir'070 fails to teach the analog-to-digital (CAN) converters, memories and digital and analog transmission lines. However based on the applicant's disclosure on Page 17 Paragraph [0079], the applicant states, "[t]he element mentioned in this paragraph [ultrasonic transmitters and receivers, digital-to-analog, analog-to-digital converters, memories and digital and analog transmission lines]...are perfectly known to the expert in the art".



**Claim 36/35/27:** Ophir'070 teaches the ultrasonic transmitters and receivers are arranged in proximity to the ultrasonic bar arranged in a housing for hand-held operation (Col. 25, Line 29-39). Ophir'070 does not explicitly teach the components be in a proximity of less than 50 cm, however, Ophir'070 does inherently teach a device with component in such close proximity of less than 50 centimeters when he explains the device as hand-held (Col. 25, Line 29-39).

**Claim 37/35/27:** Ophir'070 teaches a digital-to-analog (CNA) (Figure 6, Element 209 & Col. 23, Line 55-56). Ophir'070 fails to teach the analog-to-digital (CAN) converters. However based on the applicant's disclosure on Page 17 Second Full Paragraph, the applicant states, "[t]he element mentioned in this paragraph [ultrasonic transmitters and receivers, digital-to-analog, analog-to-digital converters, memories and digital and analog transmission lines]...are perfectly known to the expert in the art". Ophir'070 teaches the components are arranged in proximity to the ultrasonic bar arranged in a housing for hand-held operation (Col. 25, Line 29-39). Ophir'070 does not explicitly teach the components be in a proximity of less than 50 cm, however, Ophir'070 does inherently teach a device with components in such close proximity of less than 50 centimeters when he explains the device as hand-held (Col. 25, Line 29-39).

**Claim 38/37/35/27:** Ophir'070 teaches a unit, constituted of the ultrasonic transducers and their on-board electronic components, is connected to the controller by a very high-speed digital connection (Col. 28, Line 47-50).

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8. Claim 40, 45, 46, 50 & 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ophir'070 and further in view of Konofagou'459 (US Patent No. 6,270,459).

**Claim 40/27:** Ophir'070 teaches bars suitable for measuring tissular speeds (Col. 2, Line 47-54 & Col. 5, Line 29). Ophir'070 fails to teaches along directions y, x and z. However, Konofagou'459 teaches lateral and axial displacement of the transducers (Col. 8, Line 26-36). It would have been obvious to one of ordinary skill in the art to combine the teachings of Ophir'070 and Konofagou'459 in order to improve the contrast-to-noise performance (Col. 10, Line 21-24).

**Claim 45:** Ophir'070 teaches process for measuring elasticity of a human or animal organ, or viscoelastic environments (Col. 4, Line 22-33) presenting an ultrasonic signal after ultrasonic illumination and consecutively establishing a representation in two or three dimensions of the elasticity (Col. 7, Line 2-14). Ophir'070 teaches generating a low-frequency applied force or signal with an ultrasonic bar and acquiring ultrasonic signals (Col. 8, Line 65-67). Ophir'070 fails to specifically teach displacing the bar with a scanner in two perpendicular directions. However, Konofagou'459 teaches lateral and axial displacement of the transducers (Col. 8, Line 26-36). It would have been obvious to one of ordinary skill in the art to combine the teachings of Ophir'070 and Konofagou'459 in order to improve the contrast-to-noise performance (Col. 10, Line 21-24). Ophir'070 teaches generating ultrasonic images (Figure 9, Line 28). Ophir'070 teaches calculating tissular speeds (Col. 2, Line 47-54 & Col. 5, Line 29). Ophir'070

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teaches inverting the data by recovering parameters describing the viscoelastic environment (Col. 4, Line 15-21 & Col. 4, Line 33 – Col. 5, Line 28).

**Claim 46/45:** Ophir'070 teaches a low-frequency applied force or signal has a frequency between 5 Hz and 1000 Hz (Col. 3, Line 32-38).

Claim 47/45: Ophir'070 fails to teach calculating tissular deformation speeds.

Konofagou'459 teaches

**Claim 50/45:** Ophir'070 teaches acquiring the ultrasonic signals takes place while emitting an impulse with an ultrasonic transducer(s) that is reflected by particles contained in the viscoelastic environment (Col. 6, Line 52-65 & Col. 10, Line 10-18).

**Claim 51/45:** Ophir'070 does not specifically teach acquiring ultrasonic signals is realized at a cadence of  $1/T$  between 100 Hz and 100,000 Hz, where  $T$  is a period between two ultrasonic emissions. However,  $1/T$  is other definition for Hz. and Ophir'070 teaches acquiring ultrasound within that range (Col. 3, Line 32-38).

Claim 52/50/45: Ophir'070 does not specifically teach acquiring ultrasonic signals is realized at a cadence of  $1/T$  between 100 Hz and 100,000 Hz, where  $T$  is a period between two ultrasonic emissions. However,  $1/T$  is other definition for Hz. and Ophir'070 teaches acquiring ultrasound within that range (Col. 3, Line 32-38).

**Claim 53/45:** Ophir'070 teaches a displacement of the bar is realized by mechanical scanning (Figure 6, Element 205).

9. Claim 48-49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ophir'070 in view of Konofagou'459 (US Patent No. 6,270,459) and further in view of Fink'033 (US Patent No. 6,770,033).

**Claim 48/45:** Ophir'070 teaches the calculation of the tissular speeds.

Ophir'070 fails to teach measuring second derivatives of the longitudinal component of the deformation speed. However, Fink'033 teaches calculating the derivatives of the x and y displacement (Col. 8, Line 16-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Fink'033 and Ophir'070 in order to clearly view the propagation of the shear wave (Col. 8, Line 21-25). Ophir'070 and Fink'033 fail to teach the calculation along three orthogonal directions in space. However, Konofagou'459 teaches lateral and axial displacement of the transducers (Col. 8, Line 26-36). It would have been obvious to one of ordinary skill in the art to combine the teachings of Ophir'070 and Konofagou'459 in order to improve the contrast-to-noise performance (Col. 10, Line 21-24).

**Claim 49/45:** Ophir'070 teaches the calculation of the tissular speeds.

Ophir'070 fails to teach the spatial derivatives of components of the tissular speed. However, Fink'033 teaches calculating the derivatives of the x and y displacement (Col. 8, Line 16-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Fink'033 and Ophir'070 in order to clearly view the propagation of the shear wave (Col. 8, Line 21-25). Ophir'070 and Fink'033 fail to teach the calculation along three directions in space. However, Konofagou'459 teaches lateral and axial displacement of the transducers (Col. 8, Line 26-36). It would have been obvious to one of ordinary skill in the art to combine the teachings of Ophir'070 and Konofagou'459 in order to improve the contrast-to-noise performance (Col. 10, Line 21-24).

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10. Claim 48-49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ophir'070 in view of Godik'958 (US Patent No. 6,002,958) and further in view of Kruger'470 (US Patent No. 6,490,470).

**Claim 41/39/29:** Ophir'070 teaches the two bars (Col. 23, Line 38-39). Ophir'070 fails to teach the bars immersed in a hermetic container filled with a liquid. However, Godik'958 teaches the bar immersed in a hermetic container filled with a liquid (Col. 7, Line 4-7). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Ophir'070 and Godik'958 in order have a low decay of ultrasound waves (Col. 7, Line 21-24).

**Claim 42/41/39/27:** Ophir'070 and Godik'958 fail to teach a hermetic container connected to a rotator suitable for rotating the container. However, Kruger'470 teaches a container connected to a rotator suitable for rotating the container (Col. 4, Line 33-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Ophir'070, Godik'958 and Kruger'470 in order to attain greater flexibility in positioning the radiation source and other elements of the device (Col. 3, Line 20-23).

**Claim 43/41/39/27:** Ophir'070 teaches the plurality of ultrasonic transducers (Col. 23, Line 38-39) but Ophir'070 does not teach the hermetic container comprises a plurality of orifices into which a mechanical vibrator and/or an ultrasonic transducer is/are introduced. However, Godik'958 teaches an ultrasound transducer introduced into an orifice of a hermetic container or in other words "place at the cavity" (Col. 7, Line 6-7). It would have been obvious to one of ordinary skill in the art at the time of the invention to

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combine the teachings of Ophir'070 and Godik'958 for the objective of provoking local change in the tissue feature from point to point over the scanning direction and to compare the features of the nearby sites (Col. 4, Line 45-48).

**Claim 44/41/39/27:** Ophir'070 and Godik'958 fail to specifically teach the orifices are situated at 90° (degrees) from each other or one from the other. The purpose of positioning the orifices at 90° is to position either the transducer or mechanical vibrator at 90° angles (Sandrin'417, Paragraph [0021] & [0089]). Ophir'070 teaches using the ultrasound transducers laterally and axially (Abstract & Col. 17, Line 50-56 & Line 63-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Ophir'070 and Godik'958 for to provide relative and quantitative information concerning the strain (Abstract).

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Bernardi, Richard. Apparatus and Method for Indicating Mechanical Stiffness

Properties of the Body Tissue (US Patent Application No. 2003/0073905 A1).

Bonnefous, Odile. Ultrasonic Method and System for Shear Wave Parameter

Estimation (US Patent Application No. 2002/0010398 A1).

Lizzi, Frederic L. et al. Ultrasonic Sensing by Induce Tissue Motion (US Patent No. 6,488,626 B1).

Nightingale, Kathryn et al. Method and Apparatus for the Identification and

Characterization of Regions of Altered Stiffness (US Patent No. 6,371,912 B1).

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Ophir, Jonathan et al. Method and Apparatus for Measuring and Imaging of Tissue Compressibility or Compliance (US Patent No. 5,107,837).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Brown whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb

*Eleni Mantis-Mercader*  
ELEN I MANTIS-MERCADER  
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